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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,602	05/04/2001	Yao-Tseng Chen	L0461/7105(JRV/MXA)	8884

23628 7590 01/27/2003

WOLF GREENFIELD & SACKS, PC  
FEDERAL RESERVE PLAZA  
600 ATLANTIC AVENUE  
BOSTON, MA 02210-2211

EXAMINER

LY, CHEYNE D

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/27/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/849,602

Applicant(s)

CHEN ET AL.

Examiner

Cheyne D Ly

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 15, 16, 20, 47, 48, 51, 56, 57, 60, 86-90, 98 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-6, 15, 16, 20, 47, 48, 51, 56, 57, 60, 86-90, 98 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicants' response to the Restriction Requirement, Paper No. 8, filed November 26, 2002, is acknowledged.
2. This action was necessitated by the modification of the sequence election requirement. This action replaces the Office action, mailed September 18, 2002, and Applicants are required to respond to this Office action but not said previous action mailed, September 18, 2002.

### ***Election/Restrictions***

The inventions are distinct, each from the other because of the following reasons:

Restriction to one of the following inventions is required under 35 U.S.S. 121:

- I. Claims 1-5, 15, 16, 47, 48, 86-89, and 98, drawn to a method and a kit for diagnosing and determining onset, progression, or regression of colon cancer in a subject comprising contacting a sample with at least two different colon cancer-associated polypeptides, wherein the presence of specific binding is diagnostic for colon cancer classified in class 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is required.
- II. Claims 6, 20, 51, and 90, drawn to method and a kit for diagnosing and determining onset, progression, or regression, of colon cancer in a subject comprising contacting a sample with antibodies or antigen-binding fragments thereof, that bind specifically to at least two different colon cancer-associated polypeptides, and the specific binding between the antibodies or antigen-binding fragments thereof and colon cancer-associated polypeptides in the sample classified in class 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is required.

Art Unit: 1631

- III. Claims 56 and 57, drawn to protein microarray comprising at least two different colon cancer-associated polypeptides classified in class 435, subclass 287.2. If this Group is elected, then the below summarized sequence election is required.
- IV. Claim 60, drawn to a protein microarray comprising antibodies or antigen-binding fragments thereof, that specifically bind at least two different colon cancer-associated polypeptides classified in class 435, subclass 287.2. If this Group is elected, then the below summarized sequence election is required.

**Sequence Election Requirement Applicable to All Groups:**

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. **For an elected Group draw to amino acid/polypeptide sequence, the Applicants must further elect two amino acid/polypeptide sequences. For an elected Group drawn to nucleotide sequences, the Applicants must elect two nucleic sequences (See MPEP § 803.04).** It is noted that the multiple of sequence submissions for examination has resulted in an undue search burden if more than two nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic sequences effectively impossible to reasonably implement.

MPEP § 803.04 states:

Nucleotides sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent

and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction and not a specie election requirement.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I, II, III, and IV are distinct inventions because they are directed to different methods or apparatus regarding the critical limitations therein. For the method of Group I, the critical feature is the contact of the sample with at least two different colon cancer-associated polypeptides. For the method of Group II, the critical feature is the contact of a sample with antibodies or antigen-binding fragments. For Group III, the critical feature is a protein microarray comprising cancer-associated polypeptides. For Group IV, the critical feature is a protein microarray comprising antibodies or antigen-binding fragments. Further, it is acknowledged that the commonality of these methods and apparatus are colon cancer-associated polypeptides, however, the used of these polypeptides and their respective antibodies are directed toward distinct diagnostic goals support the undue search burden if they were examined together. Additionally, polypeptide, antibodies, and microarrays have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being search separately.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

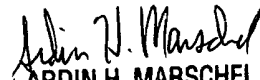
Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Application/Control Number: 09/849,602  
Art Unit: 1631

C. Dune Ly  
1/23/03

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER